

STATE OF TENNESSEE BUREAU OF TENNCARE DEPARTMENT OF FINANCE AND ADMINISTRATION 310 GREAT CIRCLE ROAD NASHVILLE, TENNESSEE

This notice is to advise you of information regarding the system used for processing <u>pharmacy claims</u> for the *TennCare Program*.

Please forward or copy the information in this notice to all pharmacy providers who may be affected by these processing changes.

ATYPICAL ANTIPSYCHOTICS:

Effective November 1, 2005, the Preferred Drug List for TennCare will be expanded to include the Atypical Antipsychotic drug class. The medications in this class include: Geodon®, Seroquel®, Clozaril®, Abilify®, Zyprexa®, Zyprexa Zydis®, Fazaclo ODT®, Risperdal®, Risperdal M-Tab®, Risperdal Consta®, clozapine, and Symbyax®. The Bureau of TennCare has decided to grandfather this class of drugs indefinitely meaning that patients who are currently on one of these medications will not be required to switch to a preferred agent or have to requalify with the criteria in order to continue receiving the medication. For example, a TennCare recipient currently receiving Zyprexa® on TennCare, will not have to stop this medication and start taking one of the preferred medications. However, low doses of atypcial antipsychotics for off-label uses (for example, Seroquel 25 to 50mg for sleep) will NOT be grandfathered.

The Preferred Drug List for the atypical antipsychotic class of medications is as follows:

PREFERRED	NON-PREFERRED
CLOZAPINE (compares to Clozaril®)	ABILIFY® (aripiprazole)
GEODON® (ziprasidone)	CLOZARIL® (clozapine)
RISPERDAL® (risperidone)	RISPERDAL M-TAB® (risperidone)
SEROQUEL® (quetiapine)	RISPERDAL CONSTA® (risperidone)
FAZACLO ODT® (clozapine)	ZYPREXA® (olanzapine)
	ZYPREXA ZYDIS® (olanzapine)

New prescriptions (i.e. prescriptions for patients who are new to therapy in this class or prescriptions that represent a change in therapy within the class), whether the prescription is for a preferred or non-preferred medication, **will require prior authorization** to ensure that specific clinical criteria are met before the agent will be approved.

Please see the Important Note at the end of this correspondence for guidance on special measures that will be in place during the month of November to assure no patient leaves the pharmacy without their medication, despite the implementation of these new requirements.

The clinical criteria attached to this class of medications is as follows:

Atypical Antipsychotic Class Criteria

- Atypical antipsychotics will be authorized for the following diagnoses:
- O BIPOLAR MANIA-ACUTE, BIPOLAR DEPRESSION, BIPOLAR MAINTENANCE, BIPOLAR MIXED STATES
- Patients should have documented in their medical record a diagnosis of bipolar disorder.

- For patients in a severe manic episode, one of the preferred atypical agents will be approved.
- For partial or non-response after a 4-week trial of a preferred atypical at the highest recommended or tolerated dose, approval will be granted for an alternative preferred atypical.
 - Patients not on a mood stabilizer (lithium, divalproex, lamotrigine, oxcarbazepine, or carbamazepine) will be required to try addition of a mood stabilizer before an alternative preferred atypical will be approved.
 - Patients currently receiving a mood stabilizer will be approved for an alternative preferred atypical.
- For partial or non-response after a 4-week trial of an appropriate dose of a second preferred atypical and a mood stabilizer, a trial of clozapine should be strongly recommended to the patient if not already tried. If refused, this should be documented in the medical record, and a trial of a non-preferred atypical agent will be approved. For patients who try clozapine and experience a partial or non-response after a 4-week trial of an appropriate dose, then a non-preferred atypical agent will be approved.

SCHIZOPHRENIA

- Patient should have documented in their medical record a diagnosis of schizophrenia or schizoaffective disorder
- For the first episode or for patients with a history of response of positive symptoms to an antipsychotic drug, one of the preferred agents should be tried. If the patient is schizoaffective and currently in an excited state, a mood stabilizer may be used. If the patient is depressed at the end of four weeks, an antidepressant may be used.
- If psychosis persists after a trial of 4 weeks at an appropriate dose of a preferred atypical, then a second preferred newer generation atypical should be tried as monotherapy for a period of four weeks. If schizoaffective, a mood stabilizer may be used.
- If psychosis persists or if moderate to severe tardive dyskinesia is present despite two trials with two different drugs from the preferred list, a trial of clozapine should be strongly recommended to the patient if not already tried. Clozapine is also recommended in patients who have made a medically serious suicide attempt. If clozapine is refused, this should be documented in the medical record, and a non-preferred atypical will be approved. For patients who try clozapine and experience a partial or non-response after a 4-week trial of an appropriate dose, then a non-preferred atypical agent will be approved.
- SCHIZOAFFECTIVE DISORDER
- o **DELUSIONAL DISORDER**
- PSYCHOTIC DEPRESSION
- o TOURETTES/SEVERE TICS
- o PSYCHOTIC DISORDER NOS
- o AGITATION OF DEMENTIA
- o PSYCHOSIS SECONDARY TO A MEDICAL CONDITION
- o AGITATION/AGGRESSION IN MENTAL RETARDATION/AUTISM
- o AGGRESSION/IMPULSE CONTROL DISORDERS
- o BRIEF PSYCHOTIC DISORDER
- SUBSTANCE-INDUCED PSYCHOTIC DISORDER (including SUBSTANCE-INDUCED WITHDRAWAL PSYCHOTIC DISORDER)
- o SEVERE REFRACTORY DEPRESSION
- SEVERE REFRACTORY OBSESSIVE COMPULSIVE DISORDER
- SEVERE REFRACTORY POST-TRAUMATIC STRESS DISORDER
- For partial or non-response following a 4-week trial at an appropriate dose of a preferred atypical, an alternative preferred atypical will be approved.
- For partial or non-response following a 4-week trial at an appropriate dose of the second preferred atypical, a non-preferred atypical may be approved.
- Atypical antipsychotics will also be authorized in situations where the prescriber can provide documented clinical evidence supporting the use of the requested medication for the requested indication.

The above criteria will allow the prescriber to obtain a preferred atypical antipsychotic. In order to obtain a non-preferred atypical antipsychotic, the recipient will have to try and fail two regimens of preferred atypical antipsychotics or have a prior authorization for the non-preferred agent from the prescriber on file. Individuals receiving a prescription for a non-preferred atypical antipsychotic, following trial and failure of 2 preferred atypicals, should be able to have the claim for the non-preferred agent automatically adjudicate. A call to the call center should not be required in these cases, as long as the claims processing system has a record of the two previous trials of the preferred atypical antipsychotic.

In addition to the above criteria, the following requirements must be met in order to receive approval for Risperdal M-tab®, Zyprexa Zydis®, Risperdal Consta®, or Symbyax®.

TRISPERIAL M-tab® and Zyprexa Zydis®

Risperdal M-tab® and Zyprexa Zydis® will only be authorized if the recipient is unable to swallow tablets, but is able to absorb PO medications.

[‡] Risperdal Consta®

Risperdal Consta @ will only be authorized if the recipient has documented non-compliance with PO atypicals or non-response due to non-compliance .

Symbyax® (H7Z) (olanzapine/fluoxetine)

All of the following must apply:

- The recipient is unable to tolerate the medications given separately
- The diagnosis must be depressive episodes associated with bipolar disorder
- The recipient is > 18 years of age and < 65 years of age

Recipients receiving prior authorization for an atypical antipsychotic will be approved only for quantities up to the drug's quantity limit. The quantity limits are as follows:

Atypical Medication	Quantity Limit
ABILIFY®	1 tablet/ day
GEODON®	2 capsules/day
RISPERDAL®	2 tablets/day or 6 mL/day
RISPERDAL M-TAB®	2 tablets/day
RISPERDAL CONSTA®	4 syringes/month
SEROQUEL®	4 tablets/day
ZYPREXA®	1 tablet/day
ZYPREXA ZYDIS®	1 tablet/day

Recipients that require quantities exceeding the above quantity limits, will need an additional prior authorization. This additional prior authorization can be obtained at the same time that the original prior authorization is given. Prescribers should note on the prior authorization form or inform the call center technician that the recipient will need an override for the quantity limit as well.

Proactive prior authorizations may be obtained from the First Health Services Clinical Call Center by calling 866-434-5524 or by fax at 866-434-5523. In order to prevent delays in a patient receiving their medication, please inform the technician or note on the faxed prior authorization that the requested prior authorization is for future use by the patient. The prior authorization form can be downloaded from the First Health/TennCare website at: https://tennessee.fhsc.com/Downloads/provider/TNRx_PAfaxform.pdf

The Grier consent decree applies and should be used in the appropriate situations. The Grier consent decree allows for patients to receive a supply of medication while a prior authorization is obtained from the prescriber. It is crucial that patients do not leave the pharmacy without a supply of medication, even if it is only for three days, assuming that there is not a clinically justified reason for refusal to fill the prescription. For more information on the Grier consent decree override codes and their appropriate use, please download the information at: https://tennessee.fhsc.com/providers/priorauth.asp or call the First Health Clinical Call Center at 866-434-5524.

IMPORTANT NOTE: Temporary Change to the Grier Override Codes for November ONLY: Due to the timing of notification for adding atypical antipsychotic medications to the PDL, the Grier override code of '8', which the pharmacy currently uses to release a 3-day supply of medication to the patient, will allow for the adjudication of the entire 31-day supply prescribed **for the month of November only.** For example, if a patient presents a new prescription for an atypical antipsychotic and has never taken a medication from this class, the Grier override code of '8' will allow for the patient to receive the entire prescribed amount. This temporary change in the Grier override code of '8' will allow the patient and pharmacy extended time to contact the prescriber and receive a prior authorization or a change to the medication prescribed.

TennCare and First Health greatly appreciate the important role pharmacists will play in providing information and assistance to patients and prescribers as these new requirements are implemented.

Please contact the First Health Clinical Call Center at 866-434-5524 or by fax at 866-434-5523 with any questions concerning these changes in the TennCare pharmacy program. The First Health Technical Call

Center can be reached at 866-434-5520. Please visit the First Health/TennCare website at http://tennessee.fhsc.com for additional information.

Thank you for your participation in the TennCare program and your commitment to assist your patients as we implement the reforms necessary to bring program costs in line with available funding.